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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,269	SEGURA ET AL.	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-15,18,21 and 22* is/are pending in the application.

4a) Of the above claim(s) *5-9,12,18 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,10,11 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/3/07, 12/9/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 41 (SEQ ID NO:42) and the species as follows: biocidal agent - antibiotic; surfactant – anionic surfactant; in the reply filed on 3/3/08 is acknowledged. The traversal is on the ground(s) that the claims have been amended and that there would not be a serious burden on the examiner to perform the search.

Due to the claim amendments the restriction requirement is amended as follows:

Group 1 (originally groups 1-45) drawn to polypeptides (claims 1-2,10-11,13-15,21-22)

Group 2 (originally group 46) drawn to polynucleotides,vector,cell,plant (claims 5-8,18)

Group 3 (originally group 47) drawn to a method of producing (claim 9)

Group 4 (originally group 48) drawn to a method of killing (claim 12)

The election of species requirement remains the same and the election of one of the original groups 1-45 is treated as an election of polypeptide. The arguments drawn to the lack of a burdensome search on the species is not found persuasive. The species require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries); the prior art applicable to one species would not likely be applicable to another species; the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

As such claims 1-2,10-11,13-15,21-22 are the elected group and the polypeptide species of SEQ ID NO:42 and the species of biocidal agent - antibiotic; surfactant – anionic surfactant are under consideration.

Applicants state that claims 1,2,10-15 read thereon or are inclusive of the elected species and invention. However claim 12 (original group 48) is in separate group and as such is withdrawn from consideration. The lack of unity of invention remains for reasons of record as discussed in the original restriction requirement (see Hong et al.).

Claims 5-9,12,18,21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/3/08.

The elected species was found to be free of the prior art. There is no claim that reads solely on the elected species. The search was extended and other art was found as cited below. No claim is allowable.

It is noted that in the course of searching for the elected species any art that reads on non-elected species is cited herein.

Claims 3-4,16-17,19-20,26 have been cancelled. As noted below claims 23-25 are not present and have been treated as cancelled claims.

Claims 1-2,10-11,13-15 are under consideration.

Claim Objections

Claim 26 is objected to because of the following informalities:

37 CFR 1.75 states that claims should be numbered consecutively. Claim 26 is listed after claim 22. There are no claims 23-25. Since claims 23-25 are not present they have been treated as cancelled claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2,10-11,13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and dependent claims 10-11,13-15 refer to a polypeptide comprising the amino acid sequence set forth in SEQ ID NO:1. The sequence listing provided by the applicant and the specification (for example page 1 lines 15-24) teach that Z is X17 or X17-R-W-L wherein X17 is F,L,R,A,G,V,Y,C, or P. It appears that applicant has made an amendment to claim 1 with respect to the variable Z although it is unclear what is to be deleted from the claim.

37 CFR 1.121(c)(2) states

> The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived.

In the instant case any deleted matter of claim 1 with respect to variable Z would be more easily perceived if double brackets were used.

It appears that applicants intention is to delete the phrase 'X17 or'. However if such phrase is deleted the claim is unclear because the claim is no longer drawn to the amino acid sequence set forth in SEQ ID NO:1 as defined in the specification and sequence listing. As noted above the sequence listing provided by the applicant and the specification (for example page 1

lines 15-24) teach that Z is X17 or X17-R-W-L wherein X17 is F,L,R,A,G,V,Y,C, or P. In particular the sequence listing states that the 19th amino acid (the position after X17) may be arginine or may be absent. As such it is unclear if the claim is open to the amino acid sequence set forth in SEQ ID NO:1 or if the sequence is limited to something else that is not the full scope of SEQ ID NO:1.

Claim 2 recites that a polypeptide consists of 18 amino acids and is extended by the amino acid sequence R-W-L. Section 2111.03 of the MPEP states that 'consisting of' is closed language. As claimed the scope of the claim is unclear as it is unclear if the claims are open ended or closed. Since the claim recites 18 amino acids it is unclear if the R-W-L extension is included in the 18 amino acids or if the R-W-L is in addition to the 18 amino acids.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that

> "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*,

the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claim 2 is drawn to a polypeptide having antimicrobial activity

(1) Level of skill and knowledge in the art:

The level of skill in the art is high.

(2) Partial structure:

As discussed above the scope of claim 2 remains unclear (see 112 2nd). For purposes of examination the claim will be given the broadest reasonable interpretation (see MPEP section 2111) such that the claims are drawn to open language. As such the claims are drawn to polypeptides of at least 18 amino acids that comprise the amino acid sequence RWL. In considering the possible variability, if one simply considered any of the 20 natural amino acids at

any of the 18 positions there would be 20^{18} possibilities. Hence, there is substantial variability in the genus.

The specification (page 41-42) recite numerous peptide sequences. However most of the peptides do not include the sequence RWL. There are 8 sequences (SEQ ID NO:38-46) that comprise RWL. However, the nine sequences represent a very small portion of the variability in the genus (at least 20^{18} possible sequences).

Since there are a substantial variety of polypeptides possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

Claim 2 recites that the polypeptide has antimicrobial activity. However, there is no disclosed correlation between structure and function. There are no common attributes or characteristics that identify polypeptides with antimicrobial activity. There is no teaching in the specification regarding what part of the structure can be varied while retaining the ability to be antimicrobial. In particular, no common sequence or common core is taught for the polypeptides. Although the peptides share the sequence RWL there is no indication that RWL is all that is needed to have antimicrobial activity. In fact, SEQ ID NO:1-37 do not include the sequence RWL. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and that there is a lack of the knowledge in the art regarding which amino acids can vary to maintain the function and thus that the applicant was not in possession of the claimed genus.

(5) Method of making the claimed invention:

The specification (specifically example 1) describes the cloning and expression of a specific polypeptide.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 2 is/are broad and generic, with respect to all possible polypeptides encompassed by the claims. The possible structural variations are many. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the polypeptides beyond those polypeptides specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient

variety of species to reflect this variance in the genus. While having written description of polypeptides identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of polypeptides embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 14-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of specific polypeptides as an antiobiotic against specific microbes, does not reasonably provide enablement for the use of all the polypeptides as antibiotics against any and all microbes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is

needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

Claims 14-15 are drawn to polypeptides for use as a medicament and for use as an antimicrobial veterinarian or human therapeutic or prophylactic agent. The claims allow for many variations within the sequence. The claims are open ended as to what microbe the antimicrobial acts on. For example, the specification page 25 lines 6-21 recites a wide range of microbes. As such the claims are open to uses against bacteria, fungi, and viruses (for example compare page 2 lines 14-15). It is noted that claim 15 is drawn to prophylaxis which is a preventative use.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Applicants discuss that there has been an increase in resistant pathogenic microorganisms (page 1 line 4-5). In the instant application, applicants show (example 1, page 39 for example) the effects of SEQ ID NO:1 on microbes and specifically test various peptides in a growth inhibition assay using E. coli (example 2 page 40-41).

With regard to the state of the art in antimicrobial peptides vant Hof et al. (Biol Chem (2001) v382 pages 597-619) review antimicrobial peptides. Vant Hof teach (page 603 section 'selective activity against different microorganisms') that that the molecular basis of selectivity of antimicrobial peptides is not completely understood and that some peptides preferentially kill

bacteria or fungi. Vant Hof teach (Table 1) that specific peptides that are active on bacteria are not necessarily active on fungi for example. Vant Hof teach that several specific peptides display antiviral activity (page 606 section 'antiviral activity), however vant Hof does not report that all peptides necessarily display antiviral activity. Vant Hof caution that the pharmacology and pharmocokinetics of antimicrobial peptides are largely unknown (page 611 first column last paragraph). Vant Hof also discuss that microbial resistance poses a problem (page 613 first column last paragraph). As such, the state of the art is unpredictable for broad range antimicrobials against for example bacteria, fungi, and viruses. With respect to the instant invention one of skill in the art would not recognize that the claimed peptides would be effective against a broad range of organisms and would not recognize that the peptides would be effective as prophylactic agents against any and all microbes.

Nagarajan (US 4,698,327) teaches that (column 1 lines 43-51), "In the search for new antibiotics, structural modification of known antibiotics is attempted whenever possible. Many antibiotics, including the glycopeptides, however, have such complex structures that even small changes are difficult to make. Furthermore, it is difficult to predict the effect these changes will make in the desired activity." (column 1, lines 43-51). As such, the state of the art is that it is unpredictable to determine which amino acid substitutions will retain function. With respect to the instant invention one of skill in the art would not recognize that all of the claimed peptides would necessarily have antimicrobial activity, especially against any and all bacteria, fungi, and viruses

(5) The relative skill of those in the art:

The level of skill in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

In the instant application, applicants show (example 1, page 39 for example) the effects of SEQ ID NO:1 on microbes. Only SEQ ID NO:1 is tested in example 1. However, there are many other peptides within the scope of claim 1. Applicants specifically test various peptides in a growth inhibition assay using E. coli (example 2 page 40-41). However, such data does not lead one to conclusions about the effectiveness against for example fungi, and viruses.

Although the claims are drawn to veterinarian and human therapeutic as well as prophylactics no examples are provided for veterinarian, human, or prophylactic uses.

(8) The quantity of experimentation necessary:

Experimentation and guidance is required in numerous areas particularly related to determining the effectiveness of the range of peptides against a range of microbes. Taken together, such experimentation and guidance is necessary because the prior art cited above teach that the state of the art is highly unpredictable. Accordingly one would be burdened with undue experimentation to determine if the compounds of the instant invention could be used for veterinarian, human, or prophylactic uses. Considering the state of the art as discussed by the references above, particularly with regards to the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate with the scope of the claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2,10,14-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Klotz et al. (Applied and Environmental Microbiology (2006) pages 6299-6315) teach that the complete genome sequence of the bacterium Nitrosococcus oceani has been determined (abstract). Klotz teach that specific transporters are present in the organism including NhaC (age 6308 last complete paragraph). The Registry database (the entry for NhaC is attached, registry number 908692-47-7 accessed April 2008) entry shows that the NhaC protein sequence from Nitrosococcus oceani includes (beginning as residue 112) GIVIFIESNMSMLVAGILS. Such a sequence reads on the sequence recited in claim 1 of the instant invention as currently interpreted (see below). Since Klotz teach Nitrosococcus oceani is in seawater the protein is part of a composition. There is no indication that the polypeptides of the current invention have been isolated or removed from a naturally occurring environment. The claimed subject matter therefore reads on a product of nature. As such claims 1,10,14-15 read on a product of nature. It is noted that Klotz does not qualify as prior art. Klotz is referenced as a universal fact to show that the claimed invention reads on a product of nature.

Huttner et al. (Gene (1998) 206, 85-91 as cited in IDS 10/3/07) teach antimicrobial peptides from sheep (abstract). Specifically Huttner teach a polypeptide sequence identified as OABac7.5 (Figure 3). The OABac7.5 sequence includes LPWRPPRPIPRPQPQPIPRWL thus meeting the limitations of claim 2 of the instant invention as currently interpreted (see below).

There is no indication that the polypeptides of the current invention have been isolated or removed from a naturally occurring environment. The claimed subject matter therefore reads on a product of nature. As such claims 2 read on a product of nature.

As discussed above the scope of claims remains unclear (see 112 2nd). For purposes of examination the claim will be given the broadest reasonable interpretation (see MPEP section 2111) such that the claims are drawn to open language (i.e. claim 1 is drawn to SEQ ID NO:1 as defined in the sequence listing and specification and claim 2 is drawn to polypeptides of any length greater than 18 amino acids).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,10,13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hong et al. (Biochemical and Biophysical Research Communications (2000) 276, 1278-1285) as cited in IDS 12/9/05).

Hong teach that a designed peptide named PGAa shows excellent anti-fungal activity (abstract). Hong teach that the PGAa peptide is of sequence GILSKLGKALKKAAKHAAKA (Figure 3) which meets the limitations of claims 1,14-15 of the instant invention as currently interpreted. Hong teach the PGAa peptide in a DPC (dodecylphosphocholine, a surfactant) micelle thus meeting the limitations of claims 10,13 of the instant invention. Hong also teach that

SDS (sodium dodecyl sulfate, an anionic surfactant) micelles were used for the compositions as well (page 1279 line 11 of sample preparation section).

As discussed above the scope of claims remains unclear (see 112 2nd). For purposes of examination the claim will be given the broadest reasonable interpretation (see MPEP section 2111) such that the claims are drawn to open language (i.e. claim 1 is drawn to SEQ ID NO:1 as defined in the sequence listing and specification).

It is noted that claims 14-15 recite that the polypeptide is 'for use as a medicament' or 'for use as an antimicrobial veterinarian or human therapeutic or prophylactic agent'. The intended use does not result in a structural difference (see for example section 2111.02 of the MPEP). Thus the composition of Hong meet the claimed limitations.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Huttner et al. (Gene (1998) 206, 85-91 as cited in IDS 10/3/07).

Huttner teach antimicrobial peptides from sheep (abstract). Specifically Huttner teach a polypeptide sequence identified as OABac7.5 (Figure 3). The OABac7.5 sequence includes LPWRPPRPIPRPQPQPIPRWL thus meeting the limitations of claim 2 of the instant invention.

As discussed above the scope of claims remains unclear (see 112 2nd). For purposes of examination the claim will be given the broadest reasonable interpretation (see MPEP section 2111) such that the claims are drawn to open language (i.e. claim 2 is drawn to polypeptides of any length greater than 18 amino acids).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,10-11,13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong et al. (Biochemical and Biophysical Research Communications (2000) 276, 1278-1285) as cited in IDS 12/9/05) and Bycroft et al. (US 5,043,176).

As discussed above Hong teach that a designed peptide named PGAa shows excellent anti-fungal activity (abstract). Hong teach that the PGAa peptide is of sequence GILSKLGKALKKAAKHAAKA (Figure 3) which meets the limitations of claims 1,14-15 of the instant invention as currently interpreted. Hong teach the PGAa peptide in a DPC (dodecylphosphocholine, a surfactant) micelle thus meeting the limitations of claims 10,13 of the

instant invention. Hong also teach that SDS (sodium dodecyl sulfate, an anionic surfactant) micelles were used for the compositions as well (page 1279 line 11 of sample preparation section). Hong also teach that micanazole (an antimicrobial) was used in the experiments (page 1279 first column section 'agar diffusion and susceptibility tests' and 'antimicrobial assays')

Hong does not expressly teach a composition that comprises an additional biocidal agent as recited in claim 11 of the instant invention.

Bycroft teach that antimicrobial compositions are known that comprise two or more antimicrobials (column 1 line 55-63). Bycroft specifically teach antimicrobial compositions containing an antimicrobial polypeptide such as a lantibiotic (claim 3) and hypothiocyanate (claim 1 for example). Bycroft teach hypothiocyanate as an active antimicrobial (column 1 line 25-27). Bycrost teach that compositions of multiple antimicrobials provide a broader spectrum of activity and decreased time of effectiveness (column 5 line 30-33).

Since both Hong and Bycroft teach antimicrobials which are known to be used for the same purpose one would be motivated to combine them. For example Bycroft teach the compositions for disenfectants (column 4 line 57) and for use in food stuffs (column 2 line 6). Further Bycrost teach that compositions of multiple antimicrobials provide a broader spectrum of activity and decreased time of effectiveness (column 5 line 30-33). It is noted that section MPEP 2144.06 of the MPEP states that it is obvious to combine two compositions which are taught to be useful for the same purpose.

In the instant case, all the claimed elements (the peptide as taught by Hong and the additional agent as taught by Bycroft) were known in the art and one skilled in the art could have

combined the elements by known methods and the combination would have yielded predictable results.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

As discussed above the scope of claims remains unclear (see 112 2nd). For purposes of examination the claim will be given the broadest reasonable interpretation (see MPEP section 2111) such that the claims are drawn to open language (i.e. claim 1 is drawn to SEQ ID NO:1 as defined in the sequence listing and specification).

It is noted that claims 14-15 recite that the polypeptide is 'for use as a medicament' or 'for use as an antimicrobial veterinarian or human therapeutic or prophylactic agent'. The intended use does not result in a structural difference (see for example section 2111.02 of the MPEP). Thus the composition of Hong meet the claimed limitations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Ronald T Niebauer/
Examiner, Art Unit 1654

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